

The Premier Research Quality Assurance Professional Organization

October 3, 2001

via UPS

Mr. Joseph Retzer
Director, Collection Services Division
U.S. Environmental Protection Agency (2823)
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Society of Quality Assurance (SQA) Comments/ICR No. 2002.02

Received

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Enforcement & Compliance Docket & Information Center

Dear Mr. Retzer:

The Society of Quality Assurance (SQA) is pleased to comment on ICR No. 2002.02 issued for the Agency's proposed Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR), which was published in 66 Federal Register 46162 (August 31, 2001).

The SQA is composed of quality assurance professionals who support work that is conducted according to EPA's Good Laboratory Practices (GLPs), Good Clinical Practices (GCPs), and Good Manufacturing Practices (GMPs). Since EPA GLP programs are among the Code of Federal Regulations Title 40 programs that are subject to CROMERRR, SQA member companies are impacted by the Agency's Proposed CROMERR Rule.

SQA welcomes efforts of the EPA to move in a direction that enables electronic reporting and record-keeping. However, SQA believes the Proposed Rule, as SQA interprets it, will pose an undue financial and resource burden on the regulated community that is not accurately articulated in the CROMERRR Preamble, Proposed Rule, or in ICR 2002.02.

Thank you for the opportunity to submit comments on the potential financial and resource burden to the regulated EPA GLP Toxic Substances Control Act [TSCA] (40 CFR Part 792) and Federal Insecticide, Fungicide and Rodenticide Act [FIFRA] (40 CFR Part 160) community.

Enclosed with this letter, SQA respectfully submits a summary and discussion, based on the EPA Public Meeting held in Washington, DC, July 11, 2000; ICR 2002.02; and SQA's understanding

SQA Comments CROMERRR/ 66 FR 46162 (August 31, 2001)

ICR No. 2002.02

Page 2 of 2

of 40 CFR Parts 3, 51, et al., "Establishment of Electronic Reporting: Electronic Records; Proposed Rule."

Sincerely,

Kathleen D. Barrowclough

CROMERRR Team Leader

SQA, Regulatory Review Committee, EPA Subcommittee

Kathleen.d.barrowclough-1@usa.dupont.com

Chathleen OBarrowelough

(302) 366-5344

Kenneth Dammers

President, Society of Quality Assurance

cc: E. Huffer, EPA, OEI, via e-mail with attachment

D. Schwartz, EPA, OEI, via e-mail with attachment

F. Liem, EPA, OECA, via e-mail with attachment

Desk Officer for EPA, OMB, via e-mail with attachment

K. Andrews, SQA Regulatory Communications Coordinator, via e-mail with attachment

E. Rosen, SQA Regulatory review Committee Chair, via e-mail with attachment

SQA Board of Directors, via e-mail with attachment

SQA Headquarters file



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SUMMARY

EPA's Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR), published in the Federal Register on August 31, 2001, allows electronic reporting and electronic record-keeping for 40 CFR regulated entities. While SQA recognizes that EPA has requested comments and is prepared to work with stakeholders to identify issues and provide a mechanism for the regulated community to express concerns, SQA is concerned that actual cost to the regulated community has been underestimated and impact on business practices is not realized by the Agency.

Key areas of concern include:

- 1) Voluntary nature of the Proposed Rule is not clearly articulated or understood;
- 2) Financial burden on the regulated community appears to be underestimated; and
- 3) Existing business practices may be halted or negatively impacted

Therefore, the SQA urges EPA to conduct a more thorough cost/benefit analysis that includes input from impacted stakeholders prior to implementing CROMERR.

Impacted stakeholders from companies submitting registration applications to EPA under the FIFRA and TSCA GLP programs could be represented by members of the SQA. Representatives familiar with FDA's 21 CFR Part 11 should also be included in the stakeholder group. Other potential stakeholders might be represented by such organizations as the American Crop Protection Association (ACPA), the American Chemistry Council (ACC, formerly the Chemical Manufacturers Association), the American Petroleum Institute (API), Association of Public Health Laboratories (APHL), Synthetic Organic Chemical Manufacturers Association (SOCMA), National Paint & Coatings Association (NPCA), Screen Printing and Graphic Imaging Association International (SPGIAI), Association of State Drinking Water Administrators (ASDWA), Association of Metropolitan Water Agencies (AMWA), Aerospace Industries Association (AIA), and/or members of industry consultants and other parties.

SQA's issues and concerns are based on participation in EPA sponsored public meetings, review of the Proposed Rule and evaluation of ICR 2002.02. If the SQA's conclusions are misdirected, SQA urges EPA to clarify the associated misunderstandings at its earliest convenience, so that the GLP regulated community can develop acceptable plans to comply with CROMERRR.

DISCUSSION

- 1) Voluntary nature of the Proposed Rule
 - The regulated TSCA and FIFRA GLP community has been generating and maintaining a variety of electronic records in support of 40 CFR regulated programs for many years. Therefore, when EPA states, as in the Summary to the Proposed Rule, "Under today's proposal, electronic document submission or electronic record-keeping will be totally voluntary...," it is unclear what the intention is for the regulated community covered by predicate rules, which has been maintaining electronic records for years. To halt electronic recordkeeping would be commensurate with halting business; therefore, maintaining records electronically is no longer a voluntary decision.
 - During the EPA/OEI Public Meeting on July 11, 2000, EPA indicated that, "...though CROMERRR is a voluntary program and [that] once a facility chooses to report electronically or maintain records electronically, it will be bound by the rule." The position that the regulated community will be held to CROMERRR requirements for electronic records if, indeed, the regulated community maintains electronic records for EPA 40 CFR directed programs, seems to reinforce the belief that compliance with CROMERRR is not a voluntary act. Again, to discontinue practices that are standard in the regulated community would essentially place companies at a significant competitive disadvantage.
 - If, as it appears from the Proposed Rule, the regulated GLP community will be held to CROMERRR requirements for electronic recordkeeping, then the analysis of financial burden to the regulated GLP community is grossly underestimated.
- 2) Financial burden on the regulated GLP community
 - From ICR 2002.02, in order to estimate capital costs incurred by the regulated community, "EPA assumes that each facility that chooses to maintain electronic records, as specified under the proposed rule, will incur a one-time capital cost of \$25,000 for the acquisition and setup of its electronic record retention system..."
 SQA believes this estimate to be grossly understated for the following reasons:
 - Most regulated facilities have numerous electronic recordkeeping systems that generate, analyze, manage, or store data for EPA 40 CFR requirements;
 - ➤ One participating SQA member company estimates capital costs of \$220,000 for one system being purchased to upgrade its analytical systems to be compliant with the FDA 21 CFR Part 11 electronic records requirements for audit trails, date and time-stamping, and archiving. EPA has indicated that CROMERRR electronic records requirements are similar to 21 CFR Part 11 requirements.
 - > The assumption by EPA that the capital cost is a one-time cost is considered by SQA to be unrealistic since technology changes rapidly and the cost of upgrades

must be factored into those capital costs. Upgrades themselves can prove costly, especially if they require new supporting operating systems or other capital expenditures.

• From ICR 2002.02, facility hour and cost burden for acquiring and setting up systems is 270 resource hours or ≈\$27,000 (Exhibit 1 in ICR 2002.02). One SQA member company estimates 306 resource hours for evaluating and validating one system against CROMERRR electronic recordkeeping requirements. If, as EPA has indicated, when a regulated facility chooses to maintain records electronically, its systems must meet CROMERRR requirements, the regulated community will incur costs for bringing numerous systems into compliance or suffer business loss from discontinuing existing electronic recordkeeping practices. The capital costs for upgrades to the system will be over and above the 306 resource hours noted above.

One SQA member facility indicates it has 30 EPA GLP directed systems that will require upgrades, while still another has estimated at least 71 systems. In both cases, these are merely the systems used in support of GLP work. There are numerous other electronic systems used to maintain records for programs such as wastewater, air emissions inventories, air permit reports, discharge monitoring reports, RCRA waste reports, etc. SQA contends that the 270 hours estimated by EPA in ICR 2002.02 does not consider the substantial resource hours and costs associated with upgrading existing systems to meet CROMERRR electronic recordkeeping requirements. SQA urges clarification on this issue from EPA.

- From ICR 2002.02, "EPA expects that, of the 162,185 facilities submitting electronic documents to EPA or the States each year, a limited number (428) will conduct electronic recordkeeping as specified under the proposed rule." SQA believes that most facilities in the GLP regulated community, as well as other entities regulated by EPA 40 CFR programs, already have electronic recordkeeping systems. If this is true, the number of entities that will be subject to CROMERRR recordkeeping requirements is significantly larger than the estimated 428 facilities and could possibly impact an additional 2000 laboratories used in support of GLP work. If this is true, where has EPA accounted for the costs associated with upgrading existing systems to meet CROMERRR recordkeeping requirements? If EPA's intent has been misconstrued, SQA urges EPA to further clarify this point.
- EPA indicates in ICR 2002.02 that, "There is no paperwork or other data item associated with initially installing an electronic recordkeeping system." Experience with EPA suggests that when criteria such as those included in CROMERRR §3.100 (a)(b)(c) for electronic records have been established, EPA has expectations around documentation that provides proof the criteria have been met. Concerning electronic computer systems, this documentation is generally validation documentation that assures the system operates as expected. The resource hours required to validate one such system varies with the complexity of the system, but is typically ≈300 hours. If EPA expects the regulated community to provide documentation that electronic

SQA Comments CROMERRR/ 66 Fed. Reg. 46162 (August 31, 2001). ICR No. 2002.02
Page 4 of 4

records meet the criteria in §3.100 (a)(b)(c), SQA contends that the ICR 2002.02 has not accurately reflected costs associated with meeting compliance to CROMERRR.

- Archiving electronic records for the retention times required by EPA TSCA and FIFRA GLPs would pose an additional financial burden on the regulated community. For example, rapid changes in technology would prompt migration of data or retention of outdated systems when new ones are implemented. Resolution of this issue is still being debated in the FDA 21 CFR Part 11 regulated community. The costs and resources associated with long-term archival storage and retrieval of electronic data have yet to be clearly defined, although estimates of the cost are substantial. Issues include the cost of migrating data and the cost of maintaining obsolete hardware or software to ensure functional capability. SQA recommends that the costs associated with long-term archival of electronic records be evaluated prior to implementation of CROMERRR, to provide a more accurate reflection of costs.
- 3) Impact on existing business practices

The GLP regulated community has maintained electronic records in support of EPA TSCA and FIFRA GLPs for many years. It is typical for the regulated community to generate, manipulate, analyze, and report data electronically. CROMERRR states, "EPA will only begin to allow electronic records to satisfy a specific EPA recordkeeping requirement once EPA has provided public notice stating that electronic records will satisfy the identified requirement."

SQA submits that significant business disruption will occur if EPA requires the regulated community to discontinue long-standing practices of maintaining records electronically. Therefore, SQA requests clarification of this requirement prior to implementation of CROMERRR.